DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

March 20, 2015

Biomate Medical Devices Technology Co., Ltd.
Mr. Wayne Chen
Quality Assurance Engineer
1F. No. 59, Luke 2nd Rd., Luzhu District
Kaohsiung City, 820
TAIWAN

Re: K142174
Trade/Device Name: Biomate Dental Implant System
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous dental implant
Regulatory Class: II
Product Code: DZE, NHA
Dated: February 7, 2015
Received: February 19, 2015

Dear Mr. Chen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Erin I. Keith, M.S.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number : K142174

Device Name: Biomate Dental Implant System

Indications for Use:

An endosseous dental implant is indicated for surgical placement in the upper and lower jaw arches, to provide a root form means for single or multiple unit prosthetic appliance attachment to restore a patient's chewing function. Implants can be placed with a conventional 2 stage surgical process with an option for transmucosal healing or they can be placed in a single stage surgical process for immediate loading. It is intended for immediate loading when good primary stability is achieved and with appropriate occlusal loading. Patients must be subject for dental treatment with endosseous implants.

Prescription Use ___ V____ AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

510(k) Summary

[As required by 21 CFR 807.92]

1. Date Prepared

March 19, 2015

2. Submitter's Information

Name of Sponsor:	Biomate Medical Devices Technology Co., Ltd.
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3. Trade Name, Common Name, Classification

Trade Name:	Biomate Dental Implant System
Common Name:	Implant, Endosseous, Root-form
Classification Name:	Implant, Endosseous, Root-form
Classification Panel:	Dental
Classification Regulation:	21 CFR 872.3640
Product Code:	DZE
Subsequent Product Code:	NHA
Device Class:	II

4. Identification of Predicate Device(s)

The identified predicates within this submission are as follows:

510(k) Number	K070562 (primary predicate)	K073268
Applicant	Mega'Gen Co., Ltd	BIOHORIZONS IMPLANT SYSTEMS, INC.
Device Name	EZ PLUS IMPLANT SYSTEMS	BIOHORIZONS INTERNAL IMPLANT SYSTEM

5. Description of the Device

The BIOMATE Dental Implant System consists of threaded dental implants in 3.3, 4.1, 4.8, 5.5 mm diameters with 8, 10, 12, 14 mm lengths. The implants

are made of commercial pure titanium and coated with the laser-modified Surface. BIOMATE Dental Implant System is comprised of Bone Type Implant, Solid Abutment, Simple Abutment, Angled Abutment, Temporary Abutment, Ball Abutment, Screw, Cover Screw, Healing Abutment. The system is designed for conventional two-stage and single stage procedures for single and multiple unit prosthetics. It is intended to be used to replace missing teeth.

6. Intended Use

An endosseous dental implant is indicated for surgical placement in the upper and lower jaw arches, to provide a root form means for single or multiple unit prosthetic appliance attachment to restore a patient's chewing function. Implants can be placed with a conventional 2 stage surgical process with an option for transmucosal healing or they can be placed in a single stage surgical process for immediate loading. It is intended for immediate loading when good primary stability is achieved and with appropriate occlusal loading. Patients must be subject for dental treatment with endosseous implants.

7. Technological Characteristics

The threaded, root-form, bone level implants are offered in 3.3, 4.1, 4.8, 5.5 mm diameters with 8, 10, 12, 14 mm length for bone type implant. The implants are made with commercial pure titanium (ASTM F67, Grade 4) and laser- modified surface (PDL™ Surface). There are no significant differences between Biomate Dental Implant System and the predicate devices that would adversely affect the use of the product. It is substantially equivalent to these devices in design, function, materials, operational principles and intended use.

8. Substantial Equivalence

The Biomate Dental Implant System has same intended use, technology, operation principle and technical characteristics with the predicate device(s). Design Verification activities were performed on Biomate Dental Implant System and all tests were verified to meet the required acceptance criteria. The verification tests demonstrate that the differences in the device do not affect the intended use of the device or raise any unsolved issues. There are no significant differences between Biomate Dental Implant System and the predicate device(s) that would adversely affect the use of the product. Biomate concludes that Biomate Dental Implant System is substantially equivalent to predicate devices. Comparative data is shown in Table 1.

9. Summary of Non-clinical Tests

Non- clinical tests followed the recommendations in the "*Class II Special Controls Guidance Document: Root-form Endosseous Dental Implant and Endosseous Dental Implant Abutments*". Tests were performed and the data demonstrate that the device is in compliance with the following standards and guidance: Biocompatibility testing- ISO 10993-3, ISO 10993-5, ISO 10993-6, ISO 10993-10, ISO 10993-11, ISO 10933-12, sterilization validation and sterility testing – ISO 11137-1, ISO 11137-2, ISO 11737-1, ISO 11737-2, and fatigue testing –ISO 14801.

10. Clinical Tests

The submission does not contain clinical data.

11. Conclusion

Biomate Dental Implant System has same intended use, technology, operation principle and technical characteristics with the predicate device(s). Based on the information and non- clinical tests provided in this premarket notification, we conclude that Biomate dental Implant System is substantially equivalent to predicate devices.

Table 1. Comparative Data

Item	Predicate K070562 (primary predicate)	Predicate K073268	Subject device
Name of device	EZ Plus Implant Systems	BioHorizons Internal Implant System	Biomate Dental Implant System
Classifications/ code	Class II, 872.3640, DZE	Class II, 872.3640, DZE	Class II, 872.3640, DZE
Prescription use	YES	YES	YES
Implant Type	Threaded, Screw-form/Root-form Bone level	Screw-form Bone level	Threaded, Root-form Bone level
Implant surface treatment	-	Treat with tricalcium phosphate blast media or hydroxylapatite coating, optional laser surface treatment	laser surface treatment
Implant to abutment connection	Internal and External Hex	-	Internal Hex
Diameter (mm)	3.3, 4.0, 5.0	3.5, 4.0, 5.0, 6.0	3.3, 4.1, 4.8, 5.5
Length(mm)	8, 10, 11, 13, 15, 18	9, 10.5, 12, 15	8, 10, 12, 14
Implant Material	Commercial pure titanium	Ti-6Al-4V	Commercially pure titanium
Abutment Material	-	-	Commercially pure titanium
Abutment Angulation	25°	-	0, 15, 25°
Sterilization	Gamma	Gamma irradiation	Gamma irradiation
Intended Use	The EZ Plus Implant Systems are intended to be surgically placed in the	BioHorizons Internal Implants are intended for used in the mandible or	An endosseous dental implant is indicated for surgical placement in the

	upper or lower jaw to support prosthetic devices, such as artificial teeth, and to restore a patient's chewing function. This may be accomplished using either a two stage surgical procedure or a single stage surgical procedure. Large angle abutments (e.g. 25°) on small diameter implants of the EZ Plus internal connection system are intended for the anterior region of the mouth and not intended for use in the posterior region of the mouth due to limited strength of the implant.	maxilla as artificial root structure for single tooth replacement or for fixed bridgework and dental retention. BioHorizons Internal Implants may be restored immediately 1) with a temporary prosthesis that is not in functional occlusion, or 2) when splinted together for multiple tooth replacement, or when stabilized with an overdenture supported by multiple implants.	upper and lower jaw arches, to provide a root form means for single or multiple unit prosthetic appliance attachment to restore a patient's chewing function. Implants can be placed with a conventional 2 stage surgical process with an option for transmucosal healing or they can be placed in a single stage surgical process for immediate loading. It is intended for immediate loading when good primary stability is achieved and with appropriate occlusal loading. Patients must be subject for dental treatment with endosseous implants